APPROVAL OF REGION IX
DRAFT QUALITY MANAGEMENT PLAN

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REGION IX

QUALITY MANAGEMENT PLAN

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FOREWORD

The Quality Management Plan of the U.S. Environmental Protection Agency Southwest Region 9 (Region 9) represents the commitment of the Region to comply with the requirements of EPA Policy and Program Requirements for the Mandatory Agency-wide Quality System, May 2000 (CIO 2105) and EPA Quality Manual for Environmental Programs, May 2000 (CIO 2105-P-01-0) to have a strong quality system in place to support all aspects of environmental data collection, analysis, and reporting. The objective of this system is to support regional management with data of known quality upon which they may make defensible and appropriate decisions. The QMP defines the planning and oversight activities that are in place relating to data collection activities conducted in the Region and defines the roles and responsibilities for implementing those activities.

1.0 Quality System Foundation

The U.S. Environmental Protection Agency uses environmental measurements collected by the Agency, other governmental agencies, grantees, regulated parties, non-governmental organizations and academia to make decisions affecting public health and the environment. The Quality System requires that each Program Office and Region establish such a system to ensure that data of known quality are generated by and for the Agency.

The Quality System is employed throughout the life cycle of a project; it informs the planning, implementation and assessment activities of a project. Sections 3.0, 4.0 and 5.0 discuss these activities in detail.

1.1 Regional Quality Assurance Goals and Policies

The responsibility to implement the system rests with all Regional staff and managers involved in data collection activities. Responsibility for developing and overseeing the implementation of the system resides with the QA Office. The Region 9 Quality Management Plan describes the management and technical processes in place to plan, implement and assess the effectiveness of QA system operations in Region 9. It defines the roles, responsibilities and authorities for implementing the Region's quality system. The benefits of having such a system in place include:

- Scientific Data Integrity – Data produced, reviewed and used is of known and documented quality.

- Reduced or Justifiable Resource Expenditures - Resource expenditures may be used more efficiently as information collection activities are better aligned with information needs.

- Effective Management of Internal and External Activities - All activities during planning, implementation and reporting stages of data generation are transparent.

- Reliable and Defensible Decisions – Decisions made based on data of known quality are more likely to be upheld.

Region 9's QA policies and activities are consistent with the requirements of CIO 2105.0, CIO 2105-P-01-0 and other relevant Agency mandates. The basic goals and specific policies are summarized below.

1.1.1 Quality Assurance Basic Goals

- Environmental data used in decision-making are of known quality.

- Data collected are of the type and quality needed and meet established objectives.

1.1.2 Quality Assurance Policies

The following policies apply to all environmental data collection activities conducted by Region 9 personnel and its contractors, grantees, and interagency agreement recipients:

- Appropriate QA planning documents (Quality Management Plan, Quality Assurance Program Plan, Quality Assurance Project Plan, Sampling and Analysis Plan, Field Sampling Plan, or Work Plan) are developed and approved for each environmental data collection activity prior to the initiation of data collection.

- Intended use(s) and data quality objectives (DQOs) of environmental data are identified prior to collection of the data in the appropriate QA planning document.

- Implementation of projects and tasks involving environmental data collection conforms to information provided in approved QA planning documents.

- Oversight of data collection activities is performed and deficiencies promptly corrected.

- Programs and projects that use existing data or data from secondary sources must have an approved QA Plan. The plan should specify the quality system that will be used to determine the suitability of the data for the proposed use.

- Quality Assurance oversight is performed to ensure that laboratories generating environmental data used in Agency and Regional decision making are providing usable and defensible results.

Overall responsibility for Quality Assurance in Region 9 resides with the Regional Administrator, who is committed to ensuring that adequate resources are allocated to accomplish Program and Regional goals. Quality Assurance is an integral part of the process of development and execution of all projects and tasks involving environmental measurement. The Regional Administrator's responsibility to Quality Assurance is outlined in Section 2.2.

The responsibility for planning, developing and implementing the Region's Quality System resides with the Regional Quality Assurance Manager. S/he reports to the Assistant Regional Administrator, Management and Technical Services Division (see Appendix A). The Assistant Regional Administrator is independent of the Divisions responsible for collecting environmental measurements. The Regional Quality Assurance Manager supervises the Quality Assurance Office. The Regional Quality Assurance Manager's responsibilities are described in Section 2.4.

Some other personnel having specific Quality Assurance responsibilities include senior staff and technical personnel located in the Air Division Air Quality Analysis Office (AQA Office) and the Superfund Emergency Response Team (see Sections 2.6.1 and 2.6.5). Quality Assurance activities within Region 9 are presented in Appendix B. Region 9 has staff throughout the Divisions that have quality assurance experience; they may support the planning document review process as requested.

2.0 Region 9 Organization

Region 9 is organized into three Offices: Regional Administrator, Public Affairs and Regional Counsel and six Divisions: Air, Communities and Ecosystems, Management and Technical Services, Superfund, Waste and Water (see Appendix C). The Region also maintains a Laboratory in Richmond, California, and small field offices in Los Angeles CA, San Diego CA and Honolulu HI. Each Division has programs and offices that may generate or oversee environmental data collection activities.

2.1 Regional Administrator

The Regional Administrator:

- Retains overall responsibility for the Quality System in Region 9 as described in this Quality Management Plan and ensures that all Regional programs comply fully with the requirements of EPA Quality Manual for Environmental Programs (CIO 2105 P-01-0).

- Ensures that quality management is an identified activity with associated resources adequate to accomplish program goals.

2.2 Assistant Regional Administrator/Senior Information Officer

The Assistant Regional Administrator:

- Supervises the QA Office, the Regional Laboratory, and Information Resources Branch
- Acts as a Senior Management liaison between the QA Office and Senior Managers in other divisions.
- Serves as the Senior Information Officer for the Region. In this capacity, s/he is responsible for resolving disputes related to the Information Quality Guidelines and the Data Quality Act (PL 106-554 HR 5658 Section 515) within Region 9.
- Retains overall responsibility for the implementation of the quality assurance program within Region 9.

2.3 Senior Management

- ♦ Have responsibility for ensuring that Division and grant recipient data collection activities conform to Regional quality assurance policies as described in this QMP.

2.4 Regional QA Manager

The Regional QA Manager (RQAM) supervises the Quality Assurance Office in the Management and Technical Services Division (see Appendix B).

The Regional Quality Assurance Manager

- Serves as manager of the Regional QA Program and supervises a group of eleven professional employees.
- Manages the development of the Regional Quality Management Plan.
- Ensures performance standards are in place requiring managers and staff to perform specific quality management functions.
- Approves the Region 9 Quality Management Plan and monitors its implementation for all internal monitoring, measurement, and data collection, review and utilization activities.
- Approves all Quality Assurance Planning Documents prepared by or on behalf of the Agency for projects or programs within the region.

- Develops policies and procedures for implementation of Quality Assurance/Quality Control within the Region.

- Reviews and signs the Quality Assurance Review Form for contracts.

- Submits annual reports to Regional management and Office of Environmental Information Quality Staff.

- Works with Headquarters Quality Staff, and Regional, State, and Tribal counterparts to promote mutual understanding and coordination in development and implementation of Quality Assurance requirements.

- Represents the Region on Quality Assurance matters as required.

- Addresses quality disputes or challenges. Where a dispute or challenge cannot be satisfactorily addressed, s/he may raise the issue to the Assistant Regional Administrator.

2.4.1 Mandatory Independence of the Regional Quality Assurance Manager and the Quality Assurance Office

Neither the Regional Quality Assurance Manager nor the Quality Assurance Office is involved with the collection and analysis of any samples, nor are they responsible for the acquisition and use of secondary data. They are not directly connected with any of the media or regulatory programs within the region.

Note: Although the Regional Laboratory reports to the Assistant Regional Administrator, as does the Quality Assurance Office, the two organizations are geographically and functionally separate. The Regional Laboratory has its own Quality Assurance system, which the QA Office audits every other year.

2.5 Quality Assurance Office

In general, it is Region 9 policy that the QA Manager and Staff may bring any issue directly to the attention of the Regional Administrator.

Usually an effort is first made to resolve a disputed QA finding at a lower level. If staff and supervisors cannot come to an agreement, the issue may be brought to the attention of the appropriate Division Director. In some instances, it may be useful to seek the advice of the Quality Staff or other experts, particularly if there is disagreement between the QA Office and the Regional Laboratory. Since the Regional Laboratory is accredited by National Environmental Laboratory Accreditation Program 9 (NELAP), that organization might be called upon to facilitate a resolution process, if necessary.

The Quality Assurance Office

- Acts as point of contact for EPA Quality Assurance concepts and practices.
- Ensures that all applicable programs delegated to State, Tribal and local governments or organizations taking environmental measurements pursuant to regulatory programs comply fully with EPA Quality Assurance requirements.
- Implements those provisions in the Regional Quality Management Plan that apply to oversight of grantees and other organizations using EPA funding to collect environmental measurements.
- Coordinates the review and approval of alternate test methods according to the requirements of the Clean Water Act (CWA) program.
- Ensures that QA training and technical support needs are identified and prioritized so that those resources are used effectively.
- Provides training to assist Federal agencies and State, Tribal, local governments, and non-profit organizations performing environmental data operations and environmental technology activities under assistance agreements with EPA.
- Performs periodic management assessments of Regional organizational units performing environmental monitoring programs.
- Performs periodic management assessments of EPA funded projects and programs conducted by State, Tribal, and local governments.
- Reviews Quality Assurance planning documents prepared by or for EPA for projects or programs by EPA staff, contractors, responsible parties, EPA-funded agencies, or grantees.
- Develops and provides guidance in the preparation and implementation of Quality Assurance Program Plans, Quality Assurance Project Plans, Sampling and Analysis Plans or other QA planning documents.
- Facilitates effective planning, implementation, and assessments of data collection systems through scoping meetings and other forms of technical support.
- Oversees Superfund technical service contracts such as the Contract Laboratory Program and the Environmental Services Assistance Team. Manages contract Delivery Orders and Task Orders for technical support of QA- related work.
- Manages and implements the Regional project specific performance evaluation sample program; assists EPA programs with the selection of appropriate

performance evaluation (PE) materials and with the development or procurement of new or customized PE samples; provides technical assistance in the interpretation of results and with laboratory corrective processes.

- Performs management and technical system audits of Regional and State environmental monitoring programs to ascertain effectiveness of QA/QC implementation; ensures that deficiencies or problems identified through audits are corrected.

- Provides assessment of data quality related to its usability for Region 9 programs and their contractors.

2.6 Regional Organizations with QA responsibilities

2.6.1 Air Division

The Air Division is responsible for implementing the provisions of the Clean Air Act (CAA) within the geographic boundaries of Region 9, including the US-Mexico border. In assuring compliance with the requirements of the CAA, the Division performs a wide variety of functions, including developing, reviewing, and implementing air quality plans (State Implementation Plans) and related regulations/rules; issuing permits; administering grants to state and local agencies, tribes, and non-governmental organizations (NGOs); and ensuring compliance with the CAA. The Division's works with the Quality Assurance Office to perform the ambient air monitoring quality assurance functions required by the Clean Air Act. Grants managed by Programs in the Division are reviewed by the Quality Assurance Office to ensure quality assurance planning document requirements are addressed.

2.6.2 Communities and Ecosystems Division

The Communities and Ecosystems Division is responsible for providing leadership and direction on regional multimedia issues, emphasizing and promoting cross-program and place-based approaches to address regional environmental issues. The Division includes the Agriculture Initiative Program, the Environmental Justice Program, and the Environmental Review Office for the region. It provides regional leadership and influences national policy on Tribal issues and on the U.S./Mexico Border Environmental Program. It manages and implements the Toxic Substances Control Act (TSCA), Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), Asbestos Hazard Emergency Response Action (AHERA), the Asbestos School Hazard Abatement Act (ASHAA), Section 313 (Toxics Release Inventory) of the Emergency Planning and Community Right-to-Know Act (EPCRA) and the Food Quality Protection Act (FQPA). The Division provides assistance and direction to U.S.-affiliated Pacific Island governments regarding environmental protection. CED also includes the Environmental Stewardship Team, which assures federal facilities compliance, leads the implementation of the Region 9 Environmental Management System, and promotes and manages the Performance Track

program. Grants managed by the Division are reviewed by the Quality Assurance Office to ensure quality assurance planning document requirements are addressed.

2.6.3 Management and Technical Services Division

The Management and Technical Services Division provides overall infrastructure support and services for EPA Region 9 including its field offices in the following areas: physical space, grant administration, financial, human resources, health and safety, information resources, environmental analysis and quality assurance. The Division provides leadership on strategic planning, performance tracking, and accountability. It is responsible for audit management, and the management integrity programs. The Division also manages implementation of the Region's mandatory quality assurance program and operates the Region 9 Laboratory and provides science support to the Region.

2.6.4 Office of Public Affairs

The Office of Public Affairs communicates Region 9 program activities and policies to its stakeholders, including the public, the media, state and local governments, state legislatures and Governors' offices, Congress, the international community, the academic community, and special interest and non-governmental organizations. In addition, the Office manages and coordinates enforcement and compliance assurance activities, and integrates enforcement data within the region. It serves as the gatekeeper for all Region 9 information products, ensuring quality, coordination and consistency with Agency priorities and standards. The Office works with the Management and Technical Services Division to ensure that the Region's communications are consistent with the Agency's Information Quality Guidelines.

2.6.5 Superfund Division

The Superfund Division is responsible for implementing the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986, the Brownfields Initiative, the Emergency Planning and Community Right-to-Know Act (EPCRA), the Clean Air Act 112(r) and the Oil Pollution Act (OPA) within EPA Region 9. The Division is charged with conducting all activities for these programs, except enforcement litigation activities. The Division works with other federal agencies, state and local agencies, and the private sector to correct uncontrolled hazardous waste site problems. The Division coordinates with the Quality Assurance Office, Regional Laboratory and the Contracts Office. The Emergency Response Team has an approved QMP to support quality assurance requirements for data collection in emergency situations. Grants administered by the Division in the Brownfields program are reviewed by the Quality Assurance Office to ensure quality assurance planning document requirements are addressed.

2.6.6 Waste Management Division

The Waste Management Division oversees, manages, and directs the activities related to the development and implementation of the hazardous waste, solid waste, pollution prevention, and underground storage tank programs under Subtitles C, D, and I of the Resource Conservation and Recovery Act (RCRA). The Division provides the overall direction, policy leadership, management, and program development of the Region's hazardous waste, solid waste, pollution prevention, and underground storage tank programs. The Division directs all policy and technical aspects of the RCRA program. The QA Office reviews planning documents for and provides other technical assistance to several offices in the Division. Grants administered by the Division are reviewed by the Quality Assurance Office to ensure quality assurance planning document requirements are addressed.

2.6.7 Water Division

The Water Division implements the provisions of the Clean Water Act (CWA), as amended, the Safe Drinking Water Act (SDWA), as amended, and the Marine Protection, Research and Sanctuaries Act (MPRSA) within the geographic boundaries of Region 9. The division has the ultimate responsibility for assuring that the chemical, physical and biological integrity of the region's waters are restored and maintained so that water pollution does not constitute a threat to public health, safety, well-being and the environment. The QA Office staff that evaluate Alternate Test Procedure applications communicate with the Division's National Pollution Discharge Elimination System (NPDES) Permits Office. Grants administered by the Division are reviewed by the Quality Assurance Office to ensure quality assurance planning document requirements are addressed.

3.0 Planning

3.1 Overview

It is Agency and Regional policy that systematic planning be used for all projects involving collection of environmental measurements. Managers make decisions based on information provided by staff, technical advice and regulatory requirements. The Quality Assurance Office supports all planning efforts by helping staff understand the level of data quality needed to make an informed decision and to weigh the short-term and long-term costs associated with that level of quality.

3.1.1 The Graded Approach

As the different programs have specific requirements for data upon which decisions are to be made, Region 9 uses a graded approach that seeks to fit the level of planning to

program requirements. This approach applies to all stages of data generation activity and to the use of environmental data subsequent to its collection. Implementation of the graded approach is discussed in the following sections.

3.2 System Level Planning

If an organization is of such size and complexity that it encompasses several programs with different data collection requirements, management support for quality is documented in a Quality Management Plan (QMP). This policy document describes the organization, management and staff roles and responsibilities, and the general systematic planning process that are expected for all programs.

3.3 Program Level Planning

The objective of environmental data collection is to provide information that may be used to implement environmental programs such as state and tribal environmental programs funded under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Clean Air Act (CAA), the Clean Water Act (CWA), the Brownfields Program, the Safe Drinking Water Act (SDWA), the Resource Conservation and Recovery Act (RCRA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). For some programs, human health-based criteria defined in the legislation or their state or tribal equivalents guide decision making; in others, presence/absence, registration or permit defined requirements drive the data collection process. The criteria associated with each program should be cited in Quality Assurance Program Plans to allow appropriate technical and policy review of the steps being taken to ensure that data generated are of known quality.

The Quality Assurance Program Plan provides a detailed record of the scope and objectives of the data collection and Quality Assurance/Quality Control (QA/QC) procedures to be used throughout a program, and defines a quality assurance system that will include development of supporting documents, such as Quality Assurance Project Plans and Sampling and Analysis Plans.

3.3.1 Graded Approach at the Organization or Program Level

The Quality Assurance Office works with grantees and other organizations to determine the type of planning document most appropriate to the program. The Quality Assurance Office may require that a Quality Management Plan with supporting QA Program Plans, or a combination QMP/QA Program Plan be prepared. In some cases, a waiver may be granted. For example, for tribal organizations with grants in only one or two media areas, preparation of Quality Assurance Project Plans may be sufficient. This is evaluated on a case by case basis. If a grantee organization has a staff of fewer than five individuals, the preparation of a QMP or a QA Program Plan is generally not resource effective. A state program generally prepares a Quality Assurance Program Plan, but may prepare a QMP or a hybrid QMP/QA Program Plan, depending on the scope and the structure of its

quality system. The QA Office works with the state or tribal organization to determine the most appropriate planning document.

As the centralized Quality Assurance Office assists all Divisions in implementing the QMP, the Divisions are not required to prepare separate QA Program Plans. Most measurement activity conducted directly by the Region is covered under project specific documents prepared by EPA staff or by contractors who work directly for EPA. The Pesticide Enforcement Program has an approved QA Program Plan that covers the activities of EPA inspectors or inspectors for state and tribal agencies working under Federal authority. The Emergency Response Office has developed a QMP, based on the need to ensure that the work conducted under emergency conditions is also of known and defensible quality.

3.4 Project Level Planning

3.4.1 Scoping Meetings

Many organizations that collect environmental measurement activities have a good understanding of the type of QA planning document their work requires. They usually proceed without consulting with the Quality Assurance Office. However, whenever appropriate, the QA Office encourages an organization to participate in a scoping meeting before a plan is written. Scoping meetings, which can be held in person or by teleconference, are attended by the EPA Project Officer or Remedial Project Manager or his or her designee, the EPA Task Manager (if an EPA contract is involved), a representative of the organization preparing the plan, and QA Office staff.

The QA Office considers scoping meetings to be integral to the effectiveness of the Region 9 Quality System. During such meetings, the participants systematically review all aspects of a project, including the objectives, decisions, sample design, collection activities, data analysis, quality control, and data assessment. Decisions are made as to the type of QA planning document that should be prepared, the appropriate analytical methods to be used, and the level of quality control necessary to achieve project objectives. Finally, the common understanding reached at a scoping meeting will facilitate review when the planning document is submitted to the QA Office.

3.4.2 Setting Project Data Quality Objectives

Data Quality Objectives (DQOs) are quantitative and qualitative statements that specify the acceptable error rates associated with environmental measurements for decision making purposes. The DQO process is designed to ensure that the type, quantity, and quality of the environmental data collected are appropriate to support specific decisions or regulatory actions. Working through the DQO process helps the project proponent define the criteria that data collection design must satisfy, including what type of data are needed, why they are needed, how they will be used and who will use them; the tolerable error rate and level of QA/QC to be implemented; an evaluation of alternative data collection and analytical approaches; the level of data review, self audits to be performed,

corrective actions to be implemented, and any constraining factors. This process of selecting DQOs, which is detailed in *Data Quality Objectives Process* [http://www.epa.gov/quality/qs-docs/g4-final.pdf], is the primary systematic planning tool for developing projects performing environmental measurements, but the Region is flexible and open to the use of other planning tools or approaches that meet project requirements.

For some routine monitoring programs and regulatory programs, the EPA National Program Offices have developed DQOs, usually in the form of regulatory standards. Those DQOs are adopted by the delegated agencies, which are primarily charged with implementing these programs. They are incorporated into planning documents for specific activities. For projects initiated in the Region, the project officer is responsible for defining, citing, or developing DQOs as part of the planning process.

3.4.3 Graded Approach at the Project Level

Region 9 supports a wide variety of environmental data collection projects. It is Region 9 policy to ensure that the type of QA planning document required and the level of QA/QC to be implemented are commensurate with the objectives of the project. For some projects, a narrative description of the quality system may be sufficient. Other projects may require a Quality Assurance Project Plan with appendices containing sampling and analytical Standard Operating Procedures. Although use of Agency or Regional guidance for preparing documents is generally recommended, some project activities do not lend themselves to these formats and EPA staff, grantees, or contractors may need to work directly with the QA Office to develop an appropriate document.

3.5 QA Annual Planning

Annual planning for the Quality Assurance Office ensures that resources are used efficiently to accomplish the Region's QA activities. Planning is undertaken at two levels: QA Office goals are included in the Region 9 Management and Technical Services Division Operating Plan and annual planning goals are included in the Quality Assurance Annual Review and Workplan (QAARWP) that is submitted to the Agency Quality Staff.

3.5.1 Regional QA Planning Process

The primary vehicles for annual planning in the region are the budget process, the Annual Commitment System (ACS), and State/EPA annual grant workplan process and the Division Operating Plans. The Deputy Regional Administrator allocates resources to each Division for the management and operation of specific programs, based on the Region's anticipated budget. Support from the QA Office helps the Region meet Agency Government Performance Results Act (GPRA) goals, program goals, and ACS commitments.

Most Regional work activities are mandated by policy and tracked via the commitments made in Program Office Operating Plans. The Operating Plan contains commitments in the form of the coming fiscal year's activities. The QA Office seeks input from the Divisions with which it works in preparing its Operating Plan.

3.5.2 National QA Planning Process

The Region's Quality Assurance Annual Report and Work Plan (QAARWP) is prepared as part of the annual Regional planning process and contains descriptions of Regional, State and Tribal activities. It also includes information about the range of activities completed, the significant fiscal year QA accomplishments and provides updates to the Regional QMP. The QAARWP is submitted by the Region to the Director of the Quality Staff in the Office of Environmental Information, who uses the information for short- and long-term planning purposes.

Section 3.5.3 QA Office Planning Process

The QA Office uses several resources to assess the adequacy of the quality system during the year, including referring the QA document review database for the status of all types of QA documents; regular meetings with the Superfund QA liaison and Regional Laboratory; regular meetings with the Air Quality Analysis Office; and follow up meetings with state and tribal grant project officers in the Water, Waste Management and Community and Ecosystem Divisions as grants are awarded during the year. Audits and trainings are scheduled based on information from these sources.

3.6 Planning Documentation

3.6.1 Policies

- All environmental measurement projects conducted by Agency personnel, its contractors, grantees and interagency agreement recipients are required to have an appropriate QA planning document approved by the QA Office prior to the initiation of data collection. The document is developed in accordance with Regional and national guidance, which is available on the QA Web page (http:/ /www .epa.gov/region09/QA/r9-QAdocs.html).

- Projects that use existing data or data from secondary sources must also have an approved QA Plan. The plan should specify the quality system that will be used to determine the suitability of the data for the proposed use.

- States or Tribes conducting regulatory programs that provide data to Region 9 are required to have their own QA systems in place. These QA systems are subject to QA Office review and approval.

- After approval, the final documents are retained by the project manager. Approved QA planning documents remain in effect for 5 years; they are up-dated annually as necessary. After 5 years, they are reviewed and revised to reflect the

current activities being performed and submitted to the QA Office for approval.

- When a state or a state program has an approved Quality Management Plan and/or QMP/QAPrP(s) in place and the QA Office has evaluated the program to ensure that it meets EPA requirements, review and approval of Quality Assurance Project Plans, Sampling and Analysis Plans and Field Sampling Plans may be delegated to the state.

3.6.2 Types of QA Planning Documents

3.6.2.1 Quality Management Plans

A Quality Management Plan outlines the structure of an organization's quality system and its underlying QA management policies. EPA generally requires that a QMP be in place for organizations with which it has contracts, grants and cooperative agreements, but the Region takes a flexible approach in implementing this policy. Region 9 requires that QMPs follow the guidance *EPA Requirements for Quality Management Plans (QA/R-2)* (EPA/240/B-01/002, March 2001). An organization may also work with the QA Office to develop an alternative approach. Such an approach must still contain the major elements found in QA/R-2, but may emphasize or delete certain sections. In some cases, Region 9 accepts documentation of an organization's quality system in a combination QMP/QA Program Plan.

3.6.2.2 Quality Assurance Program Plans

QA Program Plans are formatted and prepared according to *EPA Region 9 Guidance for the Preparation of Quality Assurance Program* Plans (R9/3.1, June, 2001), which is based on the requirements in *EPA Guidance for QA Project Plans (QA/G-5)* EPA/240/B-01/003, March 2001. The guidance expands the scope of the QA/G-5 guidance to reflect a programmatic perspective. A QA Program Plan is appropriate in situations where an organization using environmental data has multiple on-going and similar measurement activities, such as collecting monitoring data or performing inspections, or where a grant recipient serves as an umbrella organization and uses EPA funding to support its own grants and contracts.

QA Program Plans may incorporate elements of a QMP. QA Program Plans are expected to cite regulatory objectives and criteria for decision making. The program should define the documentation requirements for its activities. Either EPA guidance or independently developed guidance may be specified. QA Program Plans should include copies of relevant sampling or other field standard operating procedures (SOPs), copies of relevant laboratory QA Plans and/or SOPs or laboratory Statements of Work, and discuss data reporting and review procedures.

3.6.2.3 Quality Assurance Project Plans

The planning of project-specific data collection activities is documented in Quality

Assurance Project Plans or equivalent documents, such as Sampling and Analysis Plans (discussed in Section 3.6.2.4). QA Project Plans may be prepared by Region 9 staff or contractors, grantees, responsible parties, or contractors employed by these organizations. When implemented as written, the QA Project Plan provides a detailed record of the scope and objectives of data collection activities, procedures, and QA/QC requirements. QA Project Plans are prepared using one of the several guidance documents available on the Region 9 Quality Assurance website (http://www.epa/region09/quality/documents).

QA Project Plans may be used to describe program activities that are limited in scope in lieu of a QA Program Plan. QA Project Plans should be reviewed by the organization every year, but must be approved by the Region 9 Project Officer or Remedial Project Manager and Quality Assurance Office every 5 years.

3.6.2.4 Sampling and Analysis Plans

Sampling and Analysis Plans (SAPs) combine elements of a QA Project Plan and a Field Sampling Plan (see Section 3.6.2.5), and are prepared for one-time sampling events and are intended to be limited in scope. Although any format is acceptable provided it covers the necessary material, three guidance documents, *Sampling and Analysis Plan (SAP) Guidance and Template Version 1, EPA Analytical Services Used* (R9QA/001.1, April, 2000), *Sampling and Analysis Plan Guidance and Template, Version 2, Private Analytical Services Used* (R9QA/002.1, April, 2000), or *Sampling and Analysis Guidance and Template, Version 3, Brownfields Assessment Projects* (R9QA/008.1, May, 2008) can be found on the Region 9 website.

3.6.2.5 Field Sampling Plans

Field Sampling Plans (FSPs) are planning documents for activities taking place within a longer-term project that has a QA Project Plan in place; the larger project usually includes multiple sampling events that have distinct data quality objectives. There is no specific guidance for FSPs; an abbreviated version of *Sampling and Analysis Plan (SAP) Guidance and Template, Version 1, EPA Analytical Services Used* (R9QA/001.1, April, 2000) or *Sampling and Analysis Plan (SAP) Guidance and Template, Version 2, Private Analytical Services Used* (R9QA/002.1, April, 2000) may be used. The QA Office review focuses on sampling design, as it is assumed that information about project data quality objectives, intended uses of the data, sampling methods, analytical methods, and data review is available in the overarching QA Project Plan. Approval of an FSP is limited to the specific sampling event.

3.6.2.6 Other Quality Assurance Planning Documents

If the standard elements of a QA planning document are not relevant to a specific project, a narrative statement or expanded workplan may be sufficient. Specialized QA planning documents may be appropriate for projects involving the use of databases, secondary data or models. Alternatives such as the Region 9 guidance for recipients of wetlands grants or the Office of Research and Development QA Project Plan for research projects may

also be appropriate. Questions as to which guidance to use or approach to take should be directed to the QA Office.

3.6.3 Review and Approval of QA Planning Documents

QA planning documents must be approved by the Region 9 Quality Assurance Manager. Documents produced by responsible parties (Superfund), or by grantees (media programs) are reviewed by the QA Office. In the case of QA Program Plans or QA Project Plans for the air program, both the QA Office and the Air Division AQA Office must approve the document. The QA Office focuses its review on the quality assurance and data quality aspects of the study. The Project Officer also reviews the planning document for conformance to program requirements.

3.6.4 Quality Assurance Guidance Documents

Guidance for preparing planning documents for all types of projects may be found on the EPA website (http://www.EPA/home/quality). Region 9 has prepared several guidances to assist organizations write QA planning documents. Mentioned previously are the QA Program Plan guidance, SAP guidance documents and the QA Project Plan guidance for wetlands projects (http://www.epa/region09/qa). In addition, a CD ROM containing guidance material, a template, SOPs and references for surface water monitoring (http://www.epa.gov/region09/qa/tribes.html) is available. Although the CD ROM was developed for tribal programs, the information it contains is applicable to any surface water monitoring program.

4.0 Implementation

4.1 Overview

The quality system is implemented throughout the Regional Office. Environmental data collection activity implementation is the responsibility of the Quality Assurance Office; other relevant and ancillary activities are supported by other Region 9 Divisions and Program Offices.

4.2 Document Review

4.2.1 Quality Assurance Office Review Process

A primary responsibility of the QA Office is document review. Documents may be submitted to the QA Office by Remedial Project Managers, Project Officers or external organizations. Staff that have appropriate expertise in the subject area and document type are assigned to perform the review. A peer review process is completed before it is submitted to the QA Office for approval. Occasionally, a Project Officer or Remedial Project Manager with QA expertise will review a document. The QA Office makes the final evaluation regarding the consistency of the review with Agency and Regional QA

Office policy. The service standard for document review is 120 days for Quality Management and Program Plans, and 25 days for QA Project Plans, Sampling and Analysis Plans and Field Sampling Plans, although this is subject to negotiation with the customer.

During the course of its review, the QA Office assesses whether the document is consistent with national and QA guidance and whether the proposed QA and QC activities support the program or project data quality objectives. The QA reviewer may interact directly with planning document authors throughout the planning process (see Section 3.3). Formal comments identify areas of project QA vulnerability are prepared. The author responds to the review to address the comments and resubmits the plan. This iterative process continues until the planning document is approved.

Comments from Project Officers or Remedial Project Managers may be incorporated into the review memorandum or letter. Reviews may be transmitted independent of the QA Office or, in the case of tribes for some grants, may be sent by the QA Office directly to the tribe, as requested by the programs.

4.2.2 Other Document Review

Two offices in the Region have been delegated responsibility for review of QA documents: the Emergency Response Section in the Superfund Division and the AQA Office in the Air Division. The Emergency Response Office has an approved QMP that describes how the quality system will be implemented by the organization, which often operates within very tight deadlines. The AQA Office collaborates with the QA Office on reviews. Reviews are signed by both QA and AQA Office managers.

A State or Tribe having a quality system in place that has been described in an EPA-approved Quality Management Plan or a Quality Assurance Program Plan may receive authorization from EPA to review and approve its QA documents. The QA Office must be satisfied that the State or Tribe's implementation of its quality system is sufficiently rigorous to ensure that reviews meet EPA Region 9 standards.

4.3 Training

The QA Office provides a variety of trainings designed to meet the needs of various target audiences. The training may be generated by the QA Office based on an internal assessment or in response to a program or external request. Trainings may be designed to be informational or practical.

4.3.1 Quality Assurance Office Staff Competency

4.3.1.1 Document Review

New reviewers and reviewers working in areas outside their original expertise are trained by performing parallel reviews with senior staff until it can be demonstrated that they understand how to interpret and apply the appropriate guidance.

4.3.1.2 Technical Training

The QA Office staff are classified as chemists and environmental scientists with backgrounds that include specialized training in inorganic chemistry, organic chemistry, hydrogeology, engineering, biochemistry and biology. The staff are supported to keep current in their specialties and to expand their areas of expertise to meet emerging needs. Staff have taken training in bioassessment, air quality monitoring, chemistry, hydrology, and genomics offered by EPA or state agencies. Staff that oversee contractors as Contract Officer Representatives take contract management and technical training required to maintain the mandatory COR and federal FAC-COTR certification.

4.3.1.3 Documentation of Training

Documentation of all formal training is maintained in the individual's personnel file. Contract management training and certification is documented in the federal ACMIS database.

4.3.2 In-House and External Training

The QA Office uses surveys and interviews to identify training needs for programs and grantees. In this way, the training may be customized to meet specific needs. In general, the QA Office responds to all training requests, both for standard presentations and on a more specialized topic. The QA Office also sponsors training from outside sources. Examples of QA Office trainings include:

- Introduction to QA, for new Superfund Remedial Project Managers
- Introduction to QA, for Division managers
- Uniform Federal Policy and QA Planning, a sponsored training for federal and state agencies
- How to work with the QA Office, for Water Tribal Program Project Officers
- Preparing a QAPP, for Tribal Pesticide Enforcement Officers
- Clean Water Act 106 and 319 QA requirements, for Tribes
- QA and related Statistics, for Hawai'i Department of Health Clean Water Branch
- QA policy for collecting Volatile Organic Compounds in soil, for internal field staff

4.4 Procurement of Items and Services

4.4.1 Procurement Activities

The procurement activities in the QA Office consist of purchases, usually under $2500 (microprocurement), made on the Government Purchase Card by authorized Purchase Card Holders and purchases and contracts made by the Contracts Office in the Management and Technical Services Division. Simplified Procurements are those procurements for supplies and services under $100,000 and basically are of an off the shelf type. The Regional Contracts Office places and administers selected contracts over $100,000; places and administers orders against Government Wide Agency Contracts and Schedule Contracts of other agencies; and administers those contracts put in place for the Region by the Office of Acquisition Management at Headquarters (HQ). Contract activities for other Program Offices are developed by the user in the appropriate Division.

4.4.2 Contracts Involving Environmental Measurements

Regional procurements take place in several phases. A Program Office first identifies its requirements and develops the technical specifications, evaluation criteria, and any certifications that may be required. These are documented on an Electronic Purchase Request Form that is electronically reviewed and approved by the Section Manager and Division Director, funded by the appropriate funding control person, and submitted to the Contracting Officer (CO) for action. Changes to procurement requirements undergo the same electronic review and approval sequence.

Whether the procurement is to be made at the Headquarters or Regional Contracting Office, procurement of the requested items or services is undertaken by the CO according to Federal Agency regulations detailed in the Federal Acquisition Regulations (FAR), EPA Acquisition Regulations (EPAAR), EPA Contracts Management Manual, and the Procurement Policy Notice (PPN) Regulation No.01 -02, *Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions* March 2001, which provides guidelines for addressing EPA quality requirements for environmental data collection and use. The procurement process is documented in the contracts file pertaining to the particular action.

When environmental measurements are performed by contractors, QA requirements are integrated into the statements of work. In accordance with PPN No. 01-02, the contract-level COR generates a Quality Assurance Review Form, which defines the appropriate types of QA planning and oversight activities and is signed by the RQAM. In many cases, a Quality Management Plan or QA Project Plan is due with the proposal or soon after contract award. The QA Office may review the QA provisions of the Request for Proposal (RFP) or contract. If a contract includes environmental data collection activities, the QA Office or a designee may be a member of the technical evaluation panel. The QA Office also participates in the initial briefing session with the contractor to provide information about the Region 9 QA process. As a contract task is assigned, the appropriate QA planning document is generated and forwarded by the Work Assignment Manager (WAM) or Project Officer for QA Office review. Once the QA Office completes its review and approval of the planning document, the WAM or PO has the responsibility for performing oversight to ensure the activities covered are implemented as described.

4.4.3 Grants and Financial Assistance Agreements Involving Environmental Measurements

If States, Tribes and non-profit organizations that assist the Agency in carrying out its mission use EPA funding to perform environmental measurements, they are required under 40 CFR 31.45 to demonstrate that the organization has a quality system in place. These grants are processed through the Integrated Grants Management System (IGMS). The process generates Funding Recommendations (FR) that Project Officers must complete in order to award the grant.

In Region 9, all Funding Recommendations are routed through the QA Office for review and approval. The QA Office reviews the description of the activity being funded and the Project Officer's responses to specific QA questions against information in the QA Office document review database. A decision is made whether to add a QA requirement to the grant Terms and Conditions. These conditions inform the grantee what type of QA Planning document must be prepared for the project and provides a deadline for its submittal.

Once the recipient signs the grant and returns it to EPA, the grant condition is considered to be final. Region 9 policy does not require that QA Plans or related documents be submitted with proposals or work plans; all documents are created after the grant is funded. This allows grant funds to be used to prepare the appropriate QA planning document.

The grantee and EPA Project Officer work together to determine when the QA planning documents are to be submitted as a project deliverable. The Project Officer reviews the QA planning documents for conformance with programmatic goals and work plan objectives. The document is then forwarded to the QA Office for review. Once the QA Office completes its review and approves the planning document, oversight responsibilities revert to the Project Officer or Task Monitor, unless a special request is made for further QA Office involvement.

4.4.4 Interagency Agreements

Region 9 works with a number of other Federal agencies, including, but not limited to, the Army Corps of Engineers, the Indian Health Service, the U.S. Fish and Wildlife Service, the Bureau of Reclamation, the Bureau of Land Management, the U.S. Forest Service, the National Oceanic and Atmospheric Administration (NOAA), the Coast Guard, the Centers for Disease Control and the U.S. Geological Survey. Generally, these agencies have their own quality systems in place. However, Region 9 may require that the organization prepare a project specific QA project plan, depending on the nature of the project.

4.5 Quality Documentation and Records

4.5.1 Regional Records Management System

A records management program provides for storage and timely retrieval, secure storage and preservation of government records, minimizes potential loss of or damage to those records, and ensures cost effective use of available storage space. All employees are responsible for ensuring that Agency records are maintained in a proper manner.

Regional records management policies and guidance are contained in Regional Order 160, *Records Management Policies and Procedures, and in the Regional Records Management Manual*. The Manual contains information on topics such as records and files management, transferring records to the Federal Records Center, requesting records from the Federal Records Center, and records retention and destruction. The disposition of records is governed by the General Records Retention Schedules and EPA Retention Schedules that specify how long EPA records must be kept and when they may be destroyed.

Records management assistance and training are provided by the Regional Records Management Officer (RMO) in the Computer Systems, LAN and Telecom Program of the Management and Technical Services Division. The RMO also serves as the primary liaison with the local Federal Records Center, coordinates the transfer and retrieval of records, and assists offices in completing necessary forms and handling special situations.

4.5.2 Quality Assurance Documentation and Records

4.5.2.1 Hard Copy Records

Copies of final approved versions of planning documents should be maintained by the Project Officer for at least five years. Superfund documents are then moved to the Superfund Records Center for long term storage. The QA Office keeps a comprehensive file of all signed QA reviews and some approved plans for reference.

4.5.2.2 QA Document Tracking Database

A Document Review database, developed by the Information Resources Management Office in collaboration with the QA Office, is used to monitor and track the status of reviews or approvals of QA planning documents, reviews of reports or other documents not requiring approval and audits. Each entry in the database receives a unique document control number (DCN). The DCN tracks each document from initial submittal through one or more iterations to final approval. Once a document is approved, the database record is closed and the DCN is retired. If an approved document is amended or revised, a different DCN is assigned to the new document. The database may be sorted in any of its fields. It also contains counting capabilities, which allows workload and timeliness statistics to be calculated. For on-going grants and cooperative agreements, the database

is consulted to determine the status of QA documentation so that appropriate conditions may be added to grant Funding Recommendations (see Section 4.4.3).

4.5.3 Quality Assurance Guidance Documents

Regional QA guidance documents have been developed for use in the absence of Agency-wide guidance on particular types of projects, or when specific Regional processes need to be documented. Examples include:

- Regional guidance documents for preparing non-CLP laboratory data packages
- EPA Region 9 Guidance in the Preparation of QA Program Plans
- Wetlands Quality Assurance Project Plan Guidance
- Quality Assurance Project Plan Preparation Tool for Tribes
- Sampling and Analysis Plan (SAP) Guidance and Template, Version 2, Private Analytical Services Used (April, 2000)
- Sampling and Analysis Plan (SAP) Guidance and Template, Version 1, EPA Analytical Services Used (April, 2000)
- Sampling and Analysis Plan (SAP) Guidance and Template for Brownfields Projects (2008).

These plans are available on the EPA Region 9 Quality Assurance webpage, www.epa.gov/region09/qa with the exception of the QA Plan preparation tool for tribes, which is available in CD-ROM form by request.

Regional QA guidance documents are drafted by QA Office staff experienced in the subject area and reviewed by the RQAM and other subject-area peers before approval by the RQAM for distribution. Unique document control numbers are assigned to each document. Revisions are prepared and transmitted as needed.

4.6 Computer Hardware and Software

4.6.1 Regional Information Resources Management Policies

The Information Resources Branch within the Management and Technical Services Division has the primary responsibility for setting policy and guidance for the management and development of computer-related programs. It supports the Local Area Network (LAN), Geographic Information Systems, information security, and application development. It includes the Desktop Services Office, which is responsible for division LAN support, training and records management. Personal Computing/Laptop coordinators in each Division act as liaisons between the Information Resources Branch

and division staff. Program administrators coordinate activities relating to their databases. As these are national databases, maintenance requirements are defined by the national program offices.

Regional data are collected, processed, and managed by the program divisions. The Information Resources Branch manages the hardware, software and networking platforms. It also coordinates with the program divisions on hardware and software issues, purchases and upgrades, and pilot programs.

NIST Security Publication 800-53 requires all federal agencies have an information security program. The issue of security impacts all aspects of the Agency's information technology infrastructure. An information security program that is consistently administered across the entire Agency is critical to its ability to sustain and maintain its ongoing operations. The Agency must achieve an appropriate balance between providing safe public access to accurate environmental information and protecting the information assets of the Agency. Region 9 is fully compliant with the requirements of NIST S.P. 800-53.

4.6.1.1 Use of Computer Hardware and Software

The purchase of computer hardware and software by Region 9 and its contractors is regulated by Regional Order R2100 *Information Resources Management Hardware Policy* and Regional Order R2100.1 *Information Resources Management Software Policy*. Regional policies are designed to ensure that computer hardware and software meet program requirements and are consistent with the Agency-wide standards.

4.6.1.1.1 Assessments of Impacts of Hardware and Software Changes

Most requests for computer system development, maintenance and enhancements are initiated by clients in the program offices. The Information Resources Management Branch works closely with clients to determine their needs, options and implementation schedule.

4.6.1.1.2 Development of Software

Software applications developed in Region 9 are limited in scope. They are primarily user-oriented, and not expected to be shared outside the Region. Database applications are developed using existing software only. A typical example is a Lotus Notes document tracking system developed by the Information Resources Management Branch for program offices. Regional personnel are discouraged from developing their own software. The development process includes the following steps:

- Meetings with the user to determine user needs
- Development, validation, and verification of the application; preparation and delivery of user documentation
- Preparation by the developer of a manual on the development process

- Feedback from the user(s)

4.6.2 Standards for Computer Generated Data

Regional Information Resources Management data standards are consistent with Agency-wide standards. Regional contracts require conformance to the Regional and Agency standards for hardware, software, and data delivery format. Division justifications for computer related purchases require the Information Resources Management Branch concurrence. The monitoring of compliance is the responsibility of Project Officers.

4.6.3 Regional Environmental Data Storage and Retrieval

Some monitoring data on individual computers are part of databases developed by HQ program offices (STORET or its successor, the Water Quality Exchange and the Air Quality System [AQS]), while others are developed for specific users (e.g., Superfund contractor data from remedial investigations). The database software includes QA routines. These routines are assumed by the user to be adequate for the intended use of the database. The responsibility for quality control of data entry and corrections belongs to the program office or division that maintains the databases.

4.6.4 Geographic Information Systems

The Geographic Information Systems (GIS) laboratory is housed in the Information Resources Management Branch. The laboratory follows guidance contained in the following documents:

- OMB Circular A-16, Coordination of Geographic Information, and Related Spatial Data Activities
- OMB Circular A-130, Management of Federal Information Resources
- Latitude/Longitude Data Standard (http://www.epa.gov/edr/LatLongStandard_08112006.pdf)
- National Geospatial Data Policy (http://www.epa.gov/esd/gqc/pdf/epa_natl_geo_data_policy.pdf)
- Interim Guidance for Developing Global Positioning System Data Collection Standard Operating Procedures and Quality Assurance Project Plans (http://www.epa.gov/esd/gqc/pdf/InterimGuidance_for_GPS-SOP-QAPP.pdf)
- Guidance for Geospatial Data Quality Assurance Project Plans (http://www.epa.gov/esd/gqc/pdf/g5g-final.pdf)

The GIS laboratory uses the following data and GIS tool:

- Scribe (http://www.scribesoftware.com/)

4.7 Laboratory Program

4.7.1 Mission

The Region 9 Laboratory is a full-service state-of-the-art facility located in Richmond, CA specializing in chemical and biological analysis and field sampling services. The mission of the Laboratory is to provide quality analytical data in support of EPA regional and national programs including hazardous waste, water, air, pesticides and toxics. It primarily supports the activities of the Superfund program, for which it performs analyses generally not available through the Contract Laboratory Program.

In addition to non-routine analytical analyses, the Laboratory develops expertise and analytical techniques to support specialized regional needs. The Laboratory also provides technical support and training to internal and external laboratories and programs.

The Laboratory provides analysis of air, water, soil, solid and liquid wastes, dust and biota samples (avian, fish and mammalian tissue). Analytical chemistry capabilities include general inorganic chemistry, metals, volatile organic compounds, semi-volatile organic compounds, PCBs and pesticides. Biological analyses include toxicity testing and microbiological testing. The Laboratory also offers a variety of field services, including field sampling, and field audits.

4.7.2 Facilities

The Laboratory maintains a 40,000 square foot facility located on the grounds of the University of California Richmond Field Station. The Laboratory employs 30-35 scientists, including EPA staff and ESAT contractor staff.

4.7.3 Delivery of Laboratory Services

Before samples are analyzed in the Laboratory, a QA planning document is prepared by the requester, reviewed, and approved by the QA Office. The written plan is the basis for the communication of the requester's analytical needs to the Laboratory, which is accomplished using an electronic “Request for Analysis” Form. This form is submitted to the Regional Sample Control Coordinator, who enters the information into a database for tracking purposes.

4.7.4 Laboratory Quality Assurance Organization

QA activities are implemented under the leadership of the Laboratory's QA Officer. He is assisted by the QA Coordinator for ESAT contract, operating under a task directive under the contract.

4.7.5 Laboratory Quality Assurance System

The Laboratory is committed to monitoring and optimizing its performance through a variety of activities. The Laboratory's QA Program is documented in its QA Plan, which

is reviewed and approved by the QA Office every three years or each time a revision is prepared.

Several of the components of the Laboratory's QA system include the use of Corrective Action Reports, which highlight quality assurance issues which require investigation and correction, the use of Discrepancy Forms, which document QC analytical problems of a more routine nature, internal audits, single blind and split performance testing (PT) samples, and thorough review of all data generated by the laboratory prior to issuance of the final report.

The Laboratory routinely analyzes QA/QC samples along with field samples as a basis for determining laboratory performance. The specific QA/QC requirements vary with the method, but generally include the analysis of blanks, matrix spike/matrix spike duplicate samples, and laboratory control samples with each batch, along with a low level quantitation check and calibration checks. Other requirements would be specified in appropriate QA Planning Documents. All laboratory analyses and other processes are described in standard operating procedures. SOPs for routine activities are prepared, reviewed, and updated as needed. The responsibility for review and approval of Laboratory SOPs rests with the Chemistry Team Leader, the Biology Team Leader, the Laboratory QA Officer, and the Laboratory Director.

Data that the Laboratory generates are reviewed by the ESAT contractor, senior EPA personnel and, in selected instances, the Laboratory QA Officer. The Laboratory Director signs all final reports.

The QA Office performs quality system audits of the Laboratory every two years. The laboratory is also audited by the State of Oregon in partial fulfillment of the requirements for accreditation by the National Environmental Laboratory Accreditation Program (NELAP) in alternating years.

4.8 Standard Operating Procedures

Data collection procedures may be standardized and published as written protocols for inclusion by reference in QAPrPs, QAPjPs, SAPs, FSPs, contracts and similar documents, and for use as guidance and technical assistance documents. SOPs are prepared using *Guidance for the Preparation of Standard Operating Procedures (G-6)* (EPA/240/B-01/004, March 2001). The responsibility for preparing, updating and approving SOPs rests with the party using them. The QA Office may review these documents as part of its review of QA Planning Documents or audits it conducts, but it does not approve SOPs. The Region 9 Laboratory also has an extensive collection of SOPs, including both field and analytical procedures, which are available on its web page.

Routine activities that are performed by a Division or Office on a regular basis, especially if they are complex and/or sequential, may be usefully described in an SOP. This will ensure consistency of application, accountability for changes and will reduce data gaps

that might otherwise occur during a change in personnel or reorganization. The QA Office reviews SOPs as requested.

Region 9 does not have an overarching policy for preparing, reviewing and approving, maintaining and replacing SOPs. The QA Office reviews and provides comments for SOPs upon request, but does not approve them. The Region 9 Laboratory has an SOP policy, which is presented in the Laboratory QA Plan and lists the Laboratory SOPs on the Region 9 Laboratory webpage.

4.9 Measurement Quality Objectives/Data Quality Indicators Tables

The Region 9 QA Office has developed Measurement Quality Objective (MQO) tables of data quality indicators (DQIs) for most of the more commonly requested analytical methods. These may be used by grantees or Region 9 staff in procuring analytical services. The tables specify detailed calibration and QC requirements for each analytical method, including quality control limits and corrective action procedures. DQI tables are available on the Region 9 quality assurance web page.

4.10 Information Quality Guidelines

The Region 9 Office of Public Affairs follows the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (http://www.epa.gov/quality/informationguidelines/) in reviewing information from all Divisions that is disseminated to the public through its communication networks. The review process ensures that such products meet the performance goals stated in the guidance:

- Dissemination of information should adhere to a basic standard of quality, including objectivity, utility, and integrity
- The principles of information quality should be integrated into each step of EPA's development of information, including creation, collection, maintenance, and dissemination.
- Administrative mechanisms for correction should be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into EPA's information resources management and administrative practices.

The QA Office is working with the Office of Public Affairs and other offices within the Management and Technical Services Division to develop and implement policy and procedures that will ensure Region-wide compliance the Information Quality Guidelines.

5.0 Assessment

5.1 Overview

The audit is the standard mechanism for performing oversight of the effectiveness and adequacy of a quality system of a program or project collecting environmental measurements. During an audit, the data quality needs of the program as articulated in the quality assurance planning documents are compared against the implementation information and quality of the data obtained.

The audit process is expected to identify strengths and weaknesses; cause corrective actions to be taken to resolve problems; facilitate the initiation of changes to enhance the QA program; serve as a vehicle for providing technical assistance; enhance awareness and understanding of QA/QC policies and procedures; and provide a measurement of the effectiveness of QC in assuring the quality of data. Audits or reviews are scheduled and performed by the QA Office on Regional programs as needed and as resources allow.

QA Office staff who are responsible for conducting these audits are trained to perform these reviews and have experience in performing the types of environmental measurements. While most Region 9 QA Office staff have taken and, in some cases, provided, training in performing audits, when regulations or assignments change or new collection activities are introduced, they are strongly encouraged to enroll in training in auditing the new area. This is reflected in their Individual Development Plans. Staff performing audits must complete ethics training and financial disclosure statements, if required, each year to ensure that they are aware that there may not be any real or perceived conflict of interest in the work being assessed.

An auditor may gather information in any form, through interviews and observations, and inspection of records and data tracking documentation. The QA Office develops findings during the audit, presents preliminary findings during the exit briefing and prepares a report within a month of the audit. The auditor may consult with the audited agency to clarify issues or discuss potential corrective actions before the report is final. The results of the communication may be included in the report. Depending on the nature of the corrective action, the QA Office may follow up to ensure that the corrective action plan is being implemented or may review the status of the implementation at the next scheduled audit. If there is a question about the findings, the issue may be raised to the next level of organization management up to an including the Regional Administrator. The approach for each type of audit is presented in Table 1.

Table 1. Region 9 Audits

Type of Audit	Frequency	Assessment tool used	Reports
Division within the Regional Office review	Once every 5 years	Interview and checklist	Division Director or

of QA requirements			designee
State MSRs*	Not regularly scheduled	Audit checklist	Executive Director
Air PQAO TSA	Every three years	Audit checklist	District Executive
Regional Laboratory	Every two years	Audit checklist	Laboratory Director
Other laboratories	On demand	Audit checklist	Project Manager
Performance Evaluation Samples	As per recommendation in QAPrPs and on demand	Review of reported results	Project Manager
Data Verification/Validation	As per recommendation in QAPrPs	Review of reported results	Project Manager

*Prior to 2005, State QA programs had been audited on a variable schedule. Since 2005, we have focused on reviewing State Quality Management and Program Plans. With those reviews now up to date, we will develop a process and a schedule for auditing state MSRs. We plan to audit Arizona Department of Environmental Quality in 2009.

5.2 Assessment Tools

The assessment tools used by the Region are management systems review (MSR), technical systems audit (TSA), performance evaluation samples (PES) and data validation.

5.2.1 Management System Reviews (MSRs)

Management systems review (MSR) is an evaluation of the management of the QA program being implemented in the Region and States, including the level of management support, systematic planning and planning documentation, data quality assessment, internal audit procedures, and the effectiveness and consistency of corrective actions.

The QA Office conducts MSRs to determine whether the documented quality system is being implemented and to evaluate its effectiveness. The management and technical activities for ensuring the collection of data of known quality are reviewed, along with the roles, responsibilities, and authorities of the individuals implementing the system.

Regional MSRs are conducted in accordance with the *Guidance for Preparing, Conducting, and Reporting the Results of Management Systems Reviews* (EPA QA/G-3, March, 2003). At least one MSR is conducted each year on a Regional program, the Regional Laboratory or an EPA funded state program. However, an MSR may be

triggered by serious or persistent quality control failures or non-compliance identified through routine and standard field/lab audits and other quality checks.

5.2.2 Technical Systems Audits (TSAs)

A technical systems audit (TSA) evaluates aspects of the actual performance of specific projects or data generation activities, implementation of QA planning documents and evaluation of field and laboratory activities.

In accordance with Federal regulations at 40CFR Part 58, EPA regional offices are required to conduct TSAs of each Primary Quality Assurance Organization (PQAO) at least once every three years. A PQAO is a monitoring organization or a coordinated aggregation of such organizations that is responsible for a network of air monitoring stations which share data quality standards. A TSA is one of the ways that EPA provides oversight to ensure air quality data collected by state and local agencies meet EPA's data quality requirements.

In Region 9, there are eleven PQAOs which include: California Air Resources Board, Bay Area Air Quality Monitoring District, South Coast Air Quality Monitoring District, San Diego Air Pollution Control District, Nevada Division of Environmental Protection, Washoe County, Clark County, Hawaii Department of Health, Arizona Department of Environmental Quality, and Pima County.

Technical System Audits of state air PQAOs are conducted jointly by the Air Division AQA Office and the QA Office. Each district is audited once every three years. The AQA and QA Office perform equipment audits of other air monitoring programs as requested.

The AQA and the QA Office oversee the ESAT technician who conducts compliance audits of equipment used by air districts on a regular basis and as needed.

Field audits are conducted by staff at the Region 9 Laboratory; the QA Office may participate or conduct the audit as requested by the Laboratory field team.

The Laboratory and QA Office staff may audit laboratories working for Responsible Parties, Federal Facilities, Resource Conservation and Recovery Act (RCRA) owner/operators, National Pollution Discharge Elimination System (NPDES) dischargers and Superfund contractors upon request or as needed.

Laboratory certification audits of State, Territory, and Tribal drinking water laboratories are conducted by Regional Laboratory certification officers once every three years. Procedures and checklists for these audits are defined in the laboratory certification manuals published by the National Exposure Research Laboratory (NERL) - Cincinnati.

The QA Office has participated as an Accrediting Body evaluation team leader for the National Environmental Laboratory Accreditation Program (NELAP), performing

evaluations of the NELAP-recognized California Department of Health Services Environmental Laboratory. The QA Office chaired the national workgroup to revise NELAP Accrediting Body evaluation tools and training materials. Currently, the QA Office is a member of the Accrediting Body evaluation team.

For both field and laboratory audits, prepared reports describe when, how and by whom the audit was conducted, what specific procedures were reviewed, a summary of the findings, and recommendations for corrective action. The audit report is transmitted to the audited office, the program manager, and the Project Officer, as appropriate. The audited organization is responsible for ensuring that prompt corrective action takes place. Follow-up activities vary with the project.

5.2.3 Performance Evaluation Samples (PES)

Performance evaluation samples (PES) are samples of the chemical of interest in a known concentration that may be sent as a known performance sample or an unknown environmental sample to verify the ability of a laboratory to produce reliable data.

Performance evaluation samples are used to assess laboratory capability and performance prior to contract award and on an on-going basis as an external means to evaluate laboratory performance and ensure data reliability. Federal facilities are required to use PES on a regular basis, as indicated in planning documents. For EPA lead-sites, the EPA contractor must use them, again, as indicated in the QA Project Plan.

The QA Office provides single blind (the laboratory knows it is a performance sample but does not know the concentration) or double blind (the PE is prepared using media resembling samples being collected from a site) audit samples to check laboratory performance. The QA Office recommends the use of PES to evaluate the capability of a laboratory to perform the requested analysis and to determine whether laboratory performance is consistent for on-going projects. Laboratories also participate in regularly-scheduled EPA-wide Water Supply and Water Pollution PE studies. The Regional Laboratory uses PES in a self-evaluation program.

5.2.4 Data Review: Verification and Validation

Data review is a continuum of processes, including review or verification and validation, to determine whether data have been generated according to specifications, satisfy acceptance criteria, and are appropriate for their intended use. Data verification evaluates completeness, correctness, and compliance of data to defined methods, procedures, and control limits. Data validation expands on the data verification to assess the data and the methods used in the context of project objectives, and may bring out areas needing corrective action in future efforts. In Region 9, the term “verification” is not consistently used, and “validation” and “review” may be used interchangeably to cover a range of processes, according to a graded approach.

5.2.4.1 Roles

The QA Office performs data review primarily for Superfund Fund-lead projects and primarily through contractors, although contractors do not evaluate the usability of data for intended uses. Upon request, QA Office staff may perform data validation and oversight of data reviews for other projects from the Superfund Division (e. g., Potentially Responsible Party-lead, state-lead, Federal Facility-lead, or Brownfields) or other Divisions. All other data review defined in QA planning documents is fulfilled by the project team. The EPA Project Manager is responsible for performing the final determination as to whether the data may be used for their intended purpose; the QA Office provides technical assistance as requested.

5.2.4.2 Tiered Data Review

The QA Office uses a three-tier data evaluation system, in which the level of detail of data review increases with successive tiers. An appropriate tier is selected that meets project DQOs and financial and temporal resource constraints for data review.
Tier l is a relatively fast-paced, less intensive review of the quality control (QC) for any obvious problems with the data. Data review may be limited to reviewing reported QC results against acceptance limits without reviewing raw data such as instrument printouts and chromatograms and manual records, or performed using automated review software. The inherent risk of mischaracterizing data quality must be acceptable for project needs.

Tier 2 is a targeted review of specific components of the data package, typically specific samples or analytes of particular interest. Tiers 1 and 2 are suited to projects founded on ample confirmatory historical data. Tier 3 is the full review of all data, analyses, instrument printouts and logs, including calculation checks, which is necessary for sensitive situations and legal defensibility.

For Superfund projects, Tier 3 validation is performed with the appropriate *Superfund Functional Guidelines for Evaluating Laboratory Data* (OSWER 9240.1-46, July 2007) for organic and inorganic analyses generated through the Contract Laboratory Program (CLP). This guidance is used to validate Superfund data, and may serve as the basis for the validation procedures for other program data.

6.0 Quality Improvement

The QA Office is committed to continual improvement of the Region 9 Quality System. The staff meets regularly as an Office and as needed in designated or self-identified teams to discuss quality issues related to projects and the quality system in general. The Office may identify areas where a general policy needs to be established or changed.

Planning documents: The QA Office is developing a Guideline for planning document review. When finalized, it is expected that the Guideline may also be useful for state quality assurance programs.

Training: The QA Office supports continuous training for staff in quality assurance, as well as technical subjects related to their area of expertise and to new areas of interest or of emerging importance to the Agency and to Region 9 Divisions.

Audits: The QA Office has committed additional staff time to work with the Air Division AQA Office to complete Technical System Audits, reports and to follow up on corrective action plans on a regular schedule. Over the past three years, audits have been conducted for all state air districts. In order to keep to the state audit schedule and begin to work with the Tribal air districts, the Offices have developed a desktop audit that may be used in place of, or in addition to, an on-site audit.

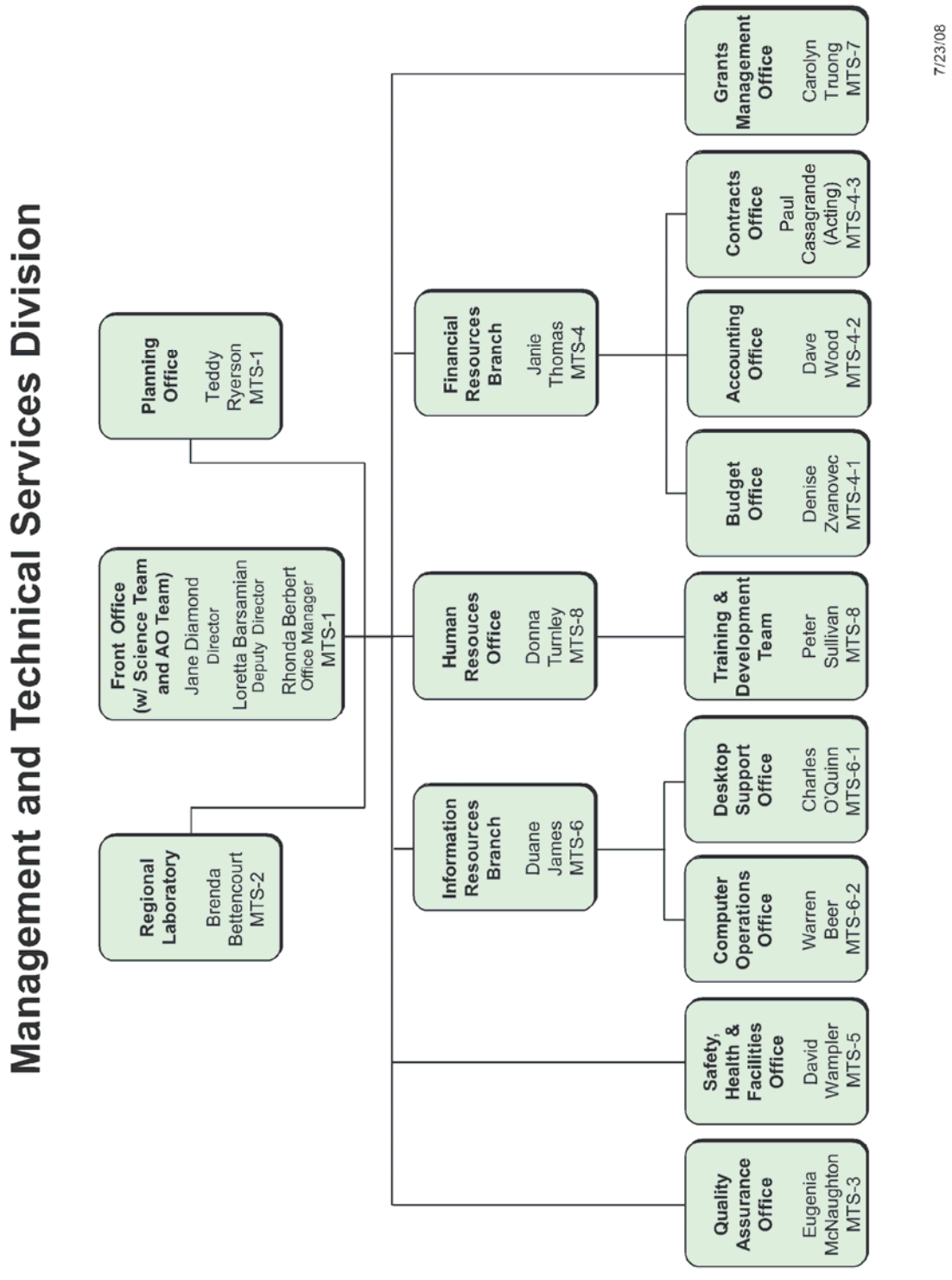
Standard Operating Procedures: The QA Office does not have a current body of SOPs to describe various office activities. We are in the process of developing an SOP for document review. This will be the first of a number of SOPs that we expect to develop over the next year. The format will follow the QA/G-6 guidance and SOPs will be reviewed every 3 years or as needed. They will be peer reviewed by staff and approved by the Regional QA Manager. SOPs that have been superseded will be archived. The QA Office SOPs will be posted on the Region 9 Quality Assurance webpage.

Information Quality Guidelines: The QA Office is working with the Information Services Branch and the Office of Public Affairs to identify Region 9 policies and procedures that demonstrate compliance with the Agency's IQGs. Once adopted, it is expected that all staff will be required to complete an on-line training on the policy.

APPENDIX A

MANAGEMENT and TECHNICAL SERVICES DIVISION

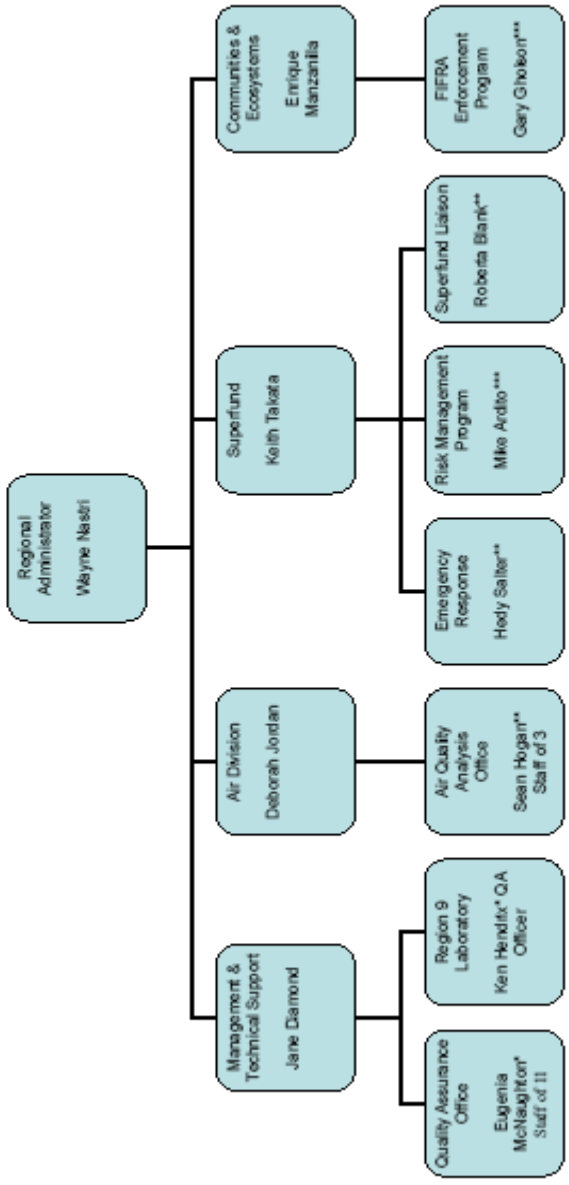
ORGANIZATION CHART


Management and Technical Services Division
Regional Laboratory
Brenda Bettencourt
MTS-2
Front Office (w/ Science Team and AO Team)
Jane Diamond
Director
Loretta Barsamian
Deputy Director
Rhonda Berbert
Office Manager
MTS-1
Planning Office
Teddy Ryerson
MTS-1
Information Resources Branch
Duane James
MTS-6
Human Resouces Office
Donna Turley
MTS-8
Financial Resources Branch
Janie Thomas
MTS-4
Quality Assurance Office
Eugenia McNaughton
MTS-3
Safety, Health & Facilities Office
David Wampler
MTS-5
Computer Operations Office
Warren Beer
MTS-6-2
Desktop Support Office
Charles O'Quinn
MTS-6-1
Training & Development Team
Peter Sullivan
MTS-8
Budget Office
Denise Zvanovec
MTS-4-1
Accounting Office
Dave Wood
MTS-4-2
Contracts Office
Paul Casagrande (Acting)
MTS-4-3
Grants Management Office
Carolyn Truong
MTS-7
7/23/08

APPENDIX B

QUALITY ASSURANCE ACTIVITIES WITHIN REGION 9

Location of Quality Assurance Activities within Region 9 Organization



* Full-time Quality Assurance responsibilities
** Part-time QA responsibilities
*** Approved QA Management or Program Plans

APPENDIX C

US EPA REGION 9

ORGANIZATION CHART

EPA United States Environmental Protection Agency
Region 9
September 2008
Office of the Regional Administrator: 415.947.8702
Regional Administrator: Wayne Nastri
Chief of Staff: Sheryl Bilbrey
Deputy Regional Administrator: Laura Yoshii
Executive Assistant: Morena Villanueva
Scheduler/Secretary: Abi Gaudario
Administrative Assistant: Michelle Counts
Office of the Regional Counsel
415.947.8705
Regional Counsel: Nancy Marvel
Acting Deputy Reg. Counsel: Allyn Stern
Office Manager:
Juanita Whitehead — 2-3937
• Enforcement
• Ethics
• Legal Counseling
Director, Southern California Field Office:
Steven John 213-244-1800
Office of Civil Rights
415.947-4286
Director: Bridget Coyle
Office Manager:
David E. De Vere — 7-4282
• Affirmative
• AEP/SEPM
• Diversity Awareness
• Counseling/Mediation
Office of Public Affairs
415.947.8700
Director: Kathleen Johnson
Associate Director: Julie Anderson
Office Manager: Mercedes Anaya — 7-4288
• Public Access to Information/Press Relations
• Web
• Partnerships: State, Congressional Liaison
• Compliance Assurance Coordination
• Pacific Islands Contact Office (Honolulu, HI)
• Environmental Education
• Children's Health
Management and Technical Services Division
415.947.8706
Director: Jane Diamond
Deputy Director: Loretta Barsamian
Office Manager: Rhonda Berbert — 2-3367
• Information Technology/Management
• $ Fund Cost Accounting
• Science Policy
• Quality Assurance
• Budget, Finance, Contracts
• Human Resources
• Health & Safety/Facilities
• Strategic Planning
• Laboratory
• Grants Management
Communities and Ecosystems Division
415.947.8704
Director: Enrique Manzanilla
Deputy Director: Fran Schultz
Associate Directors: Nate Lau,
Kathy Taylor, Clancy Tenley
Office Manager: Sue Zabor — 2-3842
• Agriculture Program
• Environmental Stewardship
• Environmental Justice
• Environmental Review
• Pesticides
• Toxics
• Tribal Program
• Pacific Islands
• US–Mexico Border
Air Division
415.947.8715
Director: Deborah Jordan
Deputy Director: Matt Haber
Associate Directors: Kerry Drake,
Colleen McKaughan, Amy Zimpfer
Office Manager: Jacqueline Scott — 7-8276
• Planning Office
• Permits Office
• Rules Office
• Enforcement Office
• Air Toxics, Radiation & Indoor Air Office
• Air Quality Analysis Office
• Grants Program Integration Office
• Clean Energy Climate Change Office
Superfund Division
415.947.8709
Director: Keith Takata
Deputy Director: Nancy Lindsay
Office Manager:
Christina Cheng — 2-3017
• Site Cleanup
• Federal Facilities and Base Closures
• Emergency Response & Planning
• Community Involvement
• Site Assessment
• Oil Pollution
• Brownfields
Waste Management Division
415.947.8708
Director: Jeff Scott
Deputy Director: Steven Barhite
Associate Directors:
Arlene Kabei, Rich Vaille, Tom Huetteman
Office Manager: Barbara Waters — 2-3310
• Pollution Prevention
• RCRA Permits/Corrective Action
• RCRA Inspections & Enforcement
• RCRA State Program Development
• Solid Waste Program
• Underground Storage Tank Program
Water Division
415.947.8707
Director: Alexis Strauss
Associate Directors:
John Kemmerer, Karen Schwinn
Nancy Woo
Office Manager:
Linda Moore — 2-3745
• Clean Water Act
• Safe Drinking Water Act
• Marine Sanctuaries Act